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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/430,034 10/29/99 BOVA

F 6256

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QM12/1012

EXAMINER

MANTIS MERCADER, E

ART UNIT

PAPER NUMBER

3737

10

DATE MAILED:

10/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/430,034

Applicant(s)

BOVA ET AL.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

FINAL ACTION***Response to Arguments***

1. Applicant's arguments filed 7/30/01 have been fully considered but they are not persuasive. Applicant's arguments regarding the "mechanically free" locator have been fully considered but they are not persuasive because an alternative embodiment is disclosed by Kormos et al.'890 which describes the "mechanically free" locator, in col. 3, lines 23-26, by stating: "...the exoskeleton material can be a mesh of a very stiff but pliable elastic mesh which is sufficiently stiff to hold the soft tissue substantially **fixed relative to itself.**" (emphasis added). This was previously cited to applicant with respect to the "mechanically free" feature. With respect to the argument that the Kormos et al.'890 reference does not teach re-use, the applicant's representative is correct. That is why the McLaurin'117 reference is used to introduce the teaching of re-use of thermoplastic material in stereotactical procedures. Therefore, the rejection is maintained and made Final.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 9, 15-16, 19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kormos et al.'890.

4. Regarding claims 9, 15-16, 19 and 23 Kormos et al.'890 teach a system of medical procedures, the system comprising:

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a locator attachable to a patient, having at least 3 fiducial markers thereon (col. 3, lines 31-44);

a medical device for performing diagnostic imaging or a therapeutic medical procedure on a patient (col. 3, line 46-59);

a sensing subsystem for sensing the positions of the fiducial markers when the patient is in a position for performing the medical procedure using the medical device (col. 4, lines 4-27);
and

wherein the locator has a registration portion for registration with a portion of a patient's body, the locator being mechanically free such that the patient is positionable without applying forces to the locator during the patient positioning, and wherein the locator is molded to fit external features of a specific patient (col. 3, lines 3-34).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-8, 10-14, 17-18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kormos et al.'890 in view of McLaurin'117.

Kormos et al.'890 teach the use of thermoplastic mesh material with markers affixed on this material, placed over the area of interest for imaging guided surgery. Kormos et al.'890 do not teach the use of this material for repeated use in imaging and therapy, and wherein the area of interest is the head/face. In the same field of endeavor, McLaurin'117 teaches the use of this

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material for repeated use in imaging and therapy, and wherein the area of interest is the head/face (see Abstract).

It would have been obvious to one skilled in the art at the time that the invention was made to have used the thermoplastic mesh material as taught by Kormos et al.'890 in subsequent procedures or at a later time as taught by McLaurin'117 in order to facilitate subsequent visits for treatment (see McLaurin'117 col. 2, lines 25-51). Furthermore, it would have been obvious to one skilled in the art at the time that the invention was made, to have used this thermoplastic material over the area of interest as demonstrated by both Kormos et al.'890 and McLaurin'117.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chader et al.'857 teach an imaging system having interactive medical instruments and methods.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

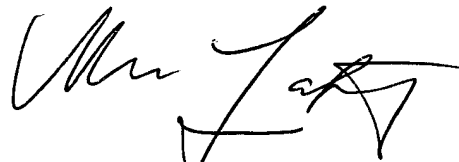
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Wed. - Wed., 7:00 a.m.-5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 703 308-7635. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-0758 for regular communications and 703 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.



Marvin M. Lateef
Supervisory Patent Examiner
Group 3700



EMM
October 7, 2001